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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,446	12/05/2003	Scott A. Burton	59427US002	9352

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
01/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/728,446	BURTON ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-35,37-39 and 45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-35,37-39 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, request for RCE and IDS, all filed 10/22/2008.

Claims 1-4, 6-35, 37-39 and 45 previously presented.

Claims 46-50 has been added by the present amendment.

Claims 1-4, 6-35, 37-39 and 45-50 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/2008 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4, 6-35, 37-39 and 45-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 of copending Application No. 10/917,002, and over claims 21-30 of copending Application No. 10/917,102. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: method of coating silver compound on a substrate comprising combing silver-containing compound with ammonium-containing compound in a solution, coating the solution on a substrate and drying the substrate. The present claims anticipate the claims of the copending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The examiner acknowledged applicants' intention to provide an appropriate response to overcome provisional obviousness-type double patenting rejection upon an indication of otherwise allowable subject matter. However, "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 7-14, 25, 37, 45, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 769,799 ('799) in view of WO 02/43743 ('743).

GB '799 teaches method for coating substrate of fabric, sheet or fibers with sparingly water soluble silver salt including dipping or wetting the substrate surface with solution comprising aqueous solution of silver salt including silver nitrate, and ammonia compound to solubilize the silver salt, followed by drying the wet substrate (page 1, lines 81-85; page 2, lines 1-5, 18-26, 30-36, 112-120; page 3, lines 112-115; the tale in page 6). The coating solution further comprises stabilizer that reads on antioxidant claimed by claims 12 and 13, and the stabilizer is added to the coating solution that is applied to the substrate, therefore, the limitations of claims 12 and 13 are met. Drying by heat will inherently remove volatile components of the coated solution and silver will remains. GB '799 teaches that the solution can be coated on medical articles surgical masks and surgeons hats (page 5, lines 123-125). The pH of the coating solution comprising the same ingredients including ammonia is expected to have the same alkaline pH value. The coated substrate is lethal to bacteria and fungi falling on its surface and remains this way for long time (page 2, lines 3-5). GB '799 teaches that dipping the substrate in the solution is carried out at temperature 60 ^{o}C 80 ^{o}C, however, temperature variation does not produce any significant change in the treated article, and even higher temperature caused color changes (page 6, lines 10-20). The reference

further teaches that the sheet is stable and resists prolonged exposure to strong sunlight, which meets the limitation of stable to at least one of visible light, UV light, electron beam, and gamma sterilization (page 5, lines 103-105, 127-128). The reference disclosed applying to an article solution containing the anions of the sparingly water soluble silver salt and also containing a basic nitrogen compound, i.e. ammonia or an amine, which serves as a solubilizer for the sparingly soluble silver salt (page 2, lines 17-27), i.e. both of silver salt and ammonium compound are in single solution prior to application to the article. In page 2, lines 17-27, the reference teaches that: "In many instances the mixture of silver salt, the light stabilizer for the silver salt, and the fungicidal salt are co-precipitated on the surfaces of the article by wetting the surfaces of the article with succession of properly chosen solutions containing the component ions of the substances, the solution containing the anions of the sparingly water soluble silver salt also containing a basic nitrogen compound, i.e. ammonia or an amine, which serves as a solubilizer for the sparingly soluble silver salt."

Although GB '799 teaches silver salts such as nitrate, however, the reference does not explicitly teach the silver salts as claimed by claims 1, 48-50.

Although GB '799 teaches insignificant effect of temperature variation of the dipping solution on the treated article and the disadvantage of higher temperature, however GB '799 does not teach specifically temperature less than 40 ^{o}C as claimed by claims 3 and 4.

Further GB '799 teaches ammonia added to the sparingly water soluble salt solution for solubilizing the solution, however, it does not explicitly teach ammonium salts claimed by claims 7 and 8.

Although GB '799 teaches coating medical articles with the disclosed solution, however, the reference does not explicitly teach coating wound dressing.

WO '743 teaches wound dressing made of polymer such as hydrocolloid or polymer fibers prepared by method comprising the steps of subjecting the polymer to aqueous solution comprising silver salts such as nitrate and carbonate, and ammonium salt such as acetate or carbonate at ambient temperature, i.e. below 40 ^{o}C, and drying the material (page 3, lines 24-30; page 4, lines 1-15; page 5, lines 3, 10-15; page 7, lines 1-3, 12-15, claim 9). The produced material is stable (page 8, line 3). The ammonium salts facilitate silver photostabilization (page 7, lines 4-7). The solution further comprises peroxide as stabilizing agent (page 7, lines 4-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with using an aqueous solution comprising sparingly water soluble silver nitrate and ammonia as disclosed by GB '799, and replace the silver nitrate with silver carbonate as disclosed by WO '743. One would have been motivated to do so because WO '743 disclosed silver nitrate and carbonate as equivalent silver salts that are appropriate silver source for combination with ammonium compound for coating wound dressing. One would have been reasonably expected coating a substrate using silver carbonate and ammonium compound and formulated stable medical devices.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound using an aqueous solution comprising sparingly water soluble silver salt and ammonia coated on the article and then drying the article as disclosed by GB '799, and further perform the step of drying the article at ambient temperature as disclosed by WO '734. One would have been motivated to do so because WO '743 teaches range of temperature up to 100 ^{o}C, and preferred ambient temperature, and also because GB '799 taught that temperature variations does not have significant effect on the treated article and taught that high temperature is disadvantageous. One would reasonably expect successfully coat a medical article with silver compound using an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article at ambient temperature with less coast and avoidance of deleterious heat effects.

Additionally, it would have been also obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonia as disclosed by GB '799, and replace the ammonia compound with ammonium carbonate as disclosed by WO '743. One would have been motivated to do so because WO '743 teaches that ammonium carbonate facilitates photostabilization of silver. One would reasonably expect coating a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonium carbonate wherein the coating is photostable.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising

sparingly water soluble silver salt and ammonia as disclosed by GB '799, and use such a coating to coat wound dressing as taught by WO '743. One would have been motivated to do so because GB '799 teaches that article coated with silver salt is lethal to bacteria and fungi falling on its surface and remains this way for long time, and also motivated by the teaching of WO '743 that wound dressing subjected to solution comprising silver salt and ammonium salts is photostable. One would reasonably expect coating a wound dressing with silver compound using an aqueous solution comprising sparingly water soluble silver salt and ammonium compound wherein the dressing is lethal to the microorganisms that come in contact with the surface of the dressing and also photostable.

8. Claims 6, 15-24, 26-35, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '799 combined with WO '743 and further in view of US 4,592,920 ('920).

The combined teachings of GB '799 and WO '743 are previously discussed as set forth in this office action.

Although GB '799 teaches sparingly water soluble silver salts and ammonium compounds for coating a substrate, however, the reference does not explicitly teach silver oxide as claimed by claims 6, 15, 27, and claims depends therefrom.

US '920 teaches coating of medical devices with coating containing antimicrobial metal that is biocompatible with body including silver oxide (abstract; col.2, lines 1-3; col.3, lines 22-25, 32-33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonia as disclosed by GB '799 combined with WO '743, and replace the silver salt with silver oxide disclosed by US '920. One would have been motivated to do so because US '920 teaches that silver oxide is biocompatible with body. One would reasonably expect coating a medical article with an aqueous solution comprising silver oxide and ammonia compound wherein the coating is safe and biocompatible with the body.

9. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of GB '799 and WO '743, and further in view US 2003/0054025 ('025).

The combined teachings of GB '799 and WO '743 are previously discussed as set forth in this office action.

Although GB '799 teaches coating of the composition containing silver salt and ammonium compound on a substrate, however, the reference does not explicitly teach spray coating as instantly claimed by claim 46.

US '025 teaches non-contact printing methods for coating medical article (abstract; paragraph 0002). The coating is a liquid medicinal agent coated on a base layer (paragraph 0029). Preferred non contact printing includes spray printing (paragraphs 0030, 0035). The medicinal agent includes silver containing compounds (paragraph 0048). The reference disclosed that after printing, the liquid composition is sufficiently dried to allow for lamination, wind-up, or storage (paragraph 0039).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article as disclosed by GB '799 combined with WO '743, and use spraying method taught by US '025 for coating the substrate. One would have been motivated to do so because US '025 teaches that spray coating of medicinal liquid containing silver compounds on a substrate is a preferred coating method. One would reasonably expect coating a substrate of medical device by spraying a liquid comprising silver salt and ammonium compound.

10. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of GB '799, WO '743 and US '920, and further in view US '025.

The combined teachings of GB '799, WO '743 and US '920 are previously discussed as set forth in this office action.

Although GB '799 teaches coating of the composition containing silver salt and ammonium compound on a substrate, however, the reference does not explicitly teach spray coating as instantly claimed by claim 47, which is taught by US '025. The teaching of US 025 is previously discussed.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver oxide and ammonia on the article as disclosed by GB '799 combined with WO '743 and US '920, and use spraying method taught by US '025 for coating the substrate. One would have been motivated to do so because US '025

teaches that spray coating of medicinal liquid containing silver compounds on a substrate is a preferred coating method. One would reasonably expect coating a substrate of medical device by spraying a liquid comprising silver oxide and ammonium compound.

Response to Arguments

11. Applicant's arguments with respect to claim1-4, 6-35, 37-39, and 45 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that GB '799 does not teach the same silver salts as instantly claimed. However, applicants' argument is moot in view of the combination of combining GB '799 with WO '743.

Applicants argue that they have done Example 2 Treatment A of GB '799, by combining the First solution (5 g AgNO3, 5g $Mg(NO3)_3$:$6H_20$, 1000 mL H_20) with the Second solution (3 g NaC1, 5g $Na2PO_4$:$12H_20$, 200 mL NH_3(Aq) and 800 mL H_2O). Prior to mixing, both solutions were clear, and upon mixing a white precipitate formed. The formation of the white precipitate indicates that the salts are not compatible in a single solution. This mixture is therefore not suitable for treating cotton because the precipitated particles would not incorporate properly into the interstices of the cotton fiber. It is not clear why the ammonia is included in the Second solution. Perhaps, the ammonia acts more as a stabilizer and less as a solubilizer. Applicants stated that they are welling to provide a Declaration providing the details of this experiment.

In comment to the experiment applicants have done and are welling to provide it in declaration, it is noticed that the experiment does not commensurate in scope with the claims because each solution contain salts other than those claimed by applicants, and the first solution contains slats other than silver salt, and the second solution contain compounds and salts of other ammonium compounds, and precipitation can happen from the reaction of other compounds. Applicants themselves admit that ammonium compounds solubilize silver salt, the fact also disclosed by the reference, therefore, the precipitation happened from applicants' experiment is not due to reaction of silver salt and ammonium compound. Objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in *Greenfield and DuPont* 197 USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88 (CCP 1971).

Applicants further argue that there is no requirement in the patent law that applicants to show why their process results in color stability, they just have to show how to carry out their process.

In response to this argument, it is argued that the prior art teaches the same article produced by the same process and performed under the same conditions. The prior art also achieved the same property desired by applicants which is photostability of the article. The burden is on applicants to show unexpected results obtained from their process and the improvement over the prior art product. The stability and non-discoloration are not unexpected results and taught by the prior art and therefore can

not rebut prima facie obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness...of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon,* 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).The burden is on applicants to show that the claimed process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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